

(4) That any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(c) The Commissioner may notify in writing the person holding an application approved pursuant to section 512(c) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under section 512(l)(1) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by section 512(l)(2) of the act; or

(2) That on the basis of new information before him evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug or animal feed are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(d) Approval of an application pursuant to section 512(c) of the act will be

withdrawn on the basis of a request for its withdrawal submitted in writing by a person holding an approved new animal drug application on the grounds that the drug subject to such application is no longer being marketed and information is included in support of this finding, provided none of the conditions cited in paragraphs (a), (b), and (c) of this section pertain to the subject drug. A written request for such withdrawal shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Withdrawal of approval of an application under the provisions of this paragraph shall be without prejudice.

(e) On the basis of the withdrawal of approval of an application for a new animal drug approved pursuant to section 512(c) of the act, the regulation published pursuant to section 512(i) of the act covering the conditions of use of such drug as provided for in the application shall be revoked.

[40 FR 13825, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 64 FR 63204, Nov. 19, 1999]

§514.116 Notice of withdrawal of approval of application.

When an approval of an application submitted pursuant to section 512 of the act is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

§514.117 Adequate and well-controlled studies.

(a) *Purpose.* The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well controlled, as used in the phrase adequate and well controlled, emphasizes